

# SPL – PET Drugs

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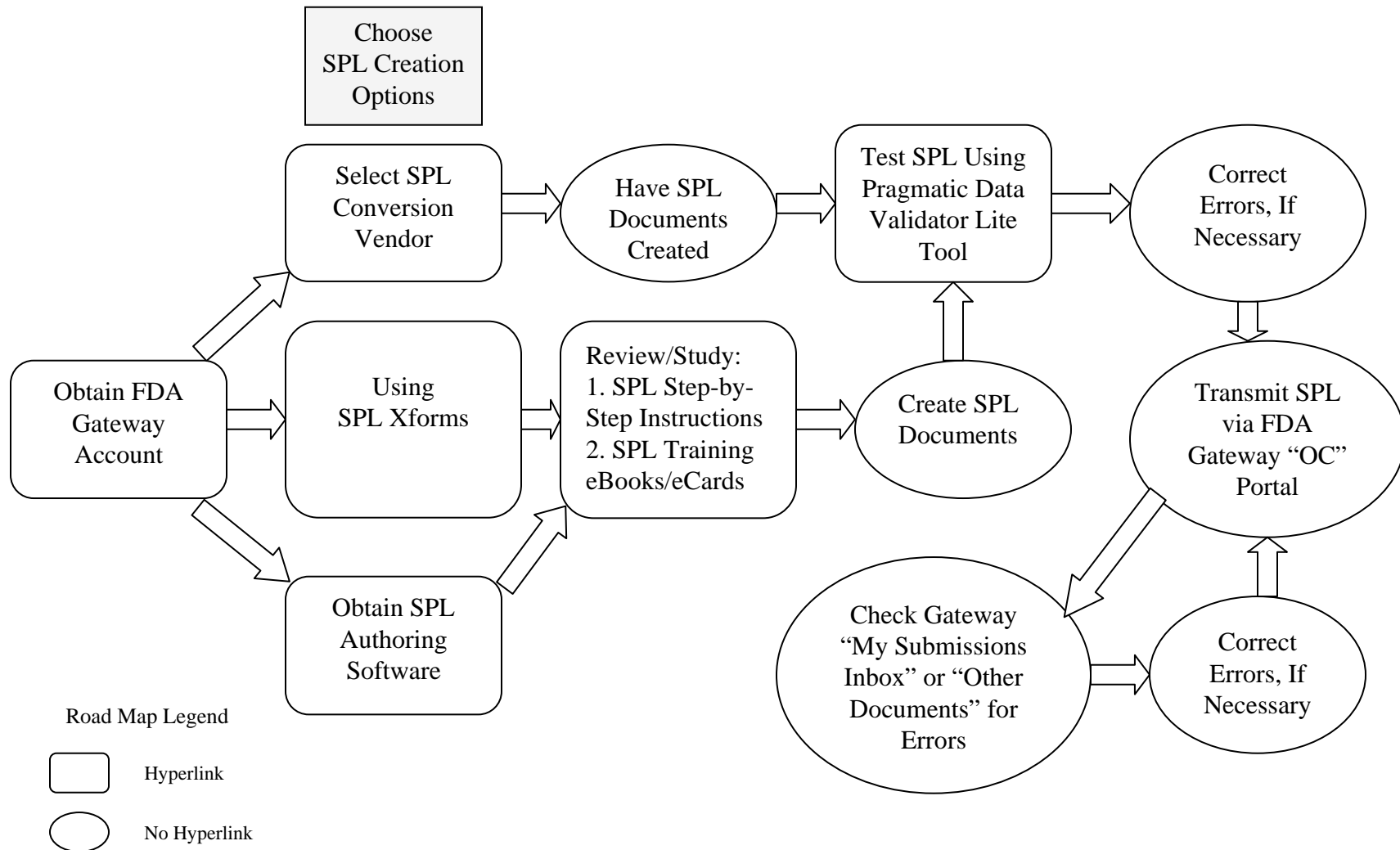
# SPL Standard

- The Structured Product Labeling (SPL) is a document markup standard approved by Health Level Seven (HL7) and adopted by FDA as a mechanism for exchanging product and facility information.
- American National Standards Institute (ANSI) accredited (SPL Release 4) – March 2009
- Beginning June 1, 2009, SPL Release Four is the current release of the standard utilized by FDA to receive and exchange product (labeling and listing) and drug establishment (drug establishment registration) data.

# Technical Terms Glossary

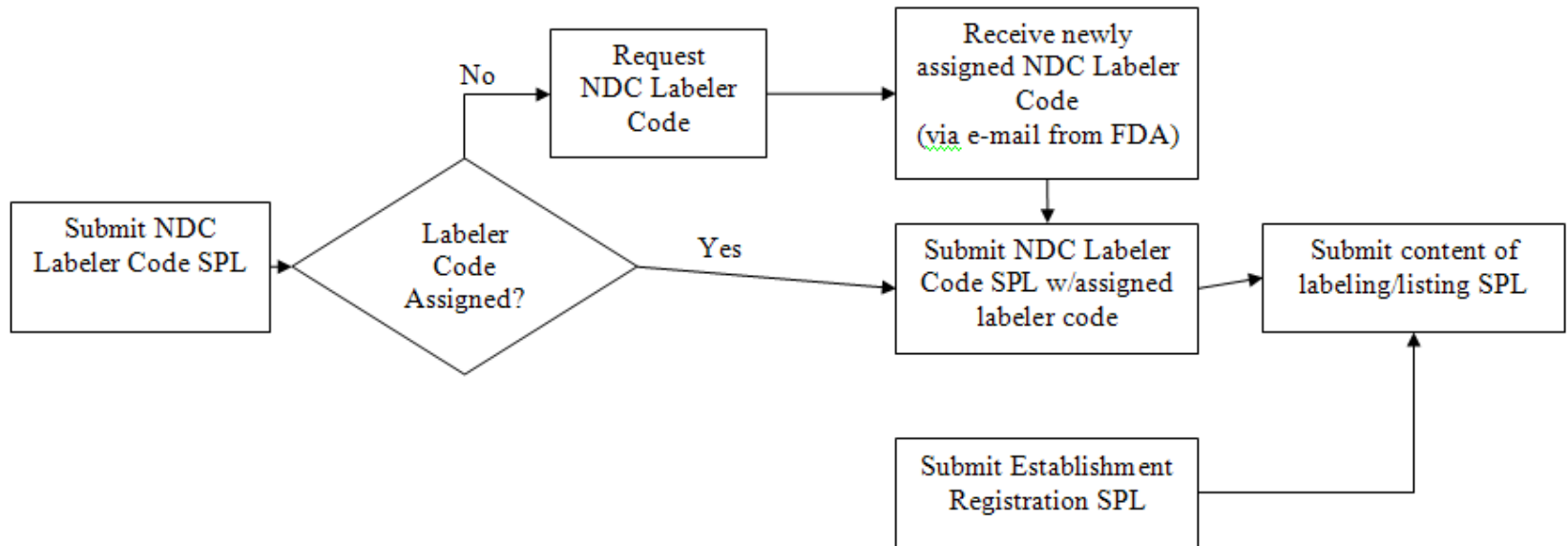
Term	Definition
Core ID	•A unique identifier which the FDA ESG assigns to every submission and uses for reference purposes
Document Root ID	•Globally Unique Identifier (GUID) and is unique for each version of the document. Also referred as “root ID,” “ID,” “document ID,” or “document root ID.”
Effective Time	•Provides a date reference to the SPL document version or a section including the year, month and day as yyyyymmdd.
GUID	•Globally Unique Identifier (used as the SPL document root ID, setID, or section IDs)
SetID	•Globally Unique Identifier (GUID) and is a unique identifier for the document that remains constant through all versions/revisions of the document.
UUID	•Universal Unique Identifier (UUID) Synonymous w/GUID (see definition for GUID)
Version Number	•Integer greater than zero that provides a sequence to the versions of the document.

# “Road Map” Creation & Submission

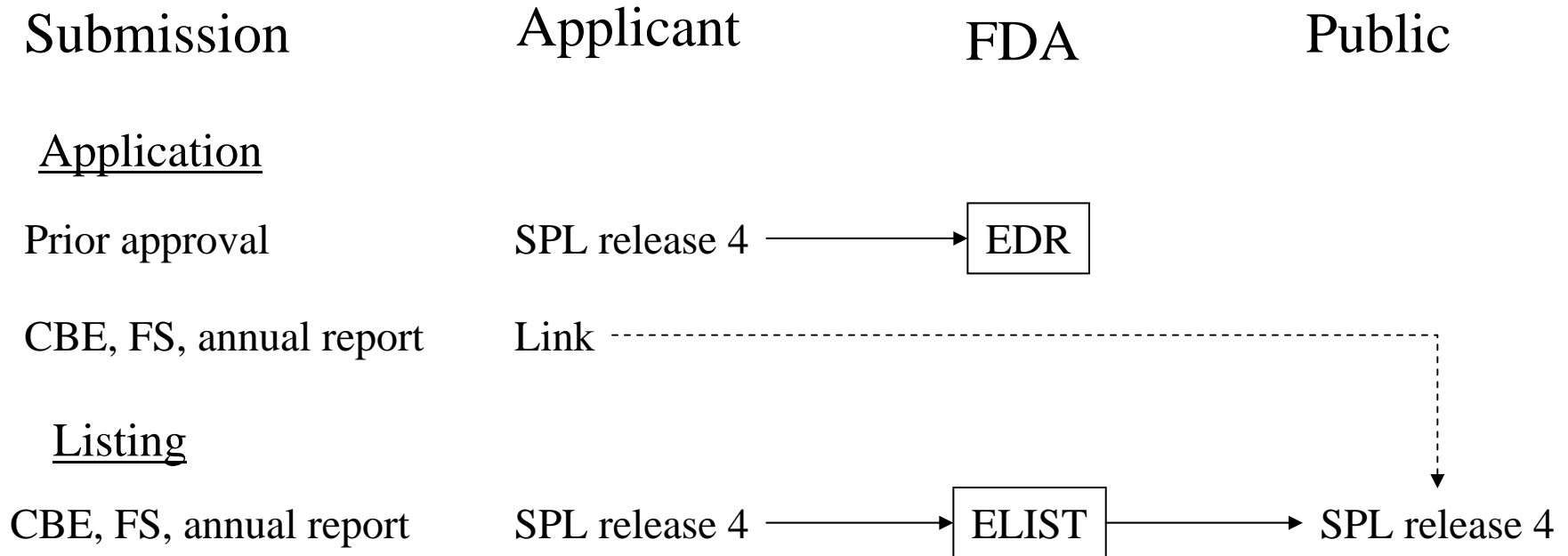


# SPL Submission Process

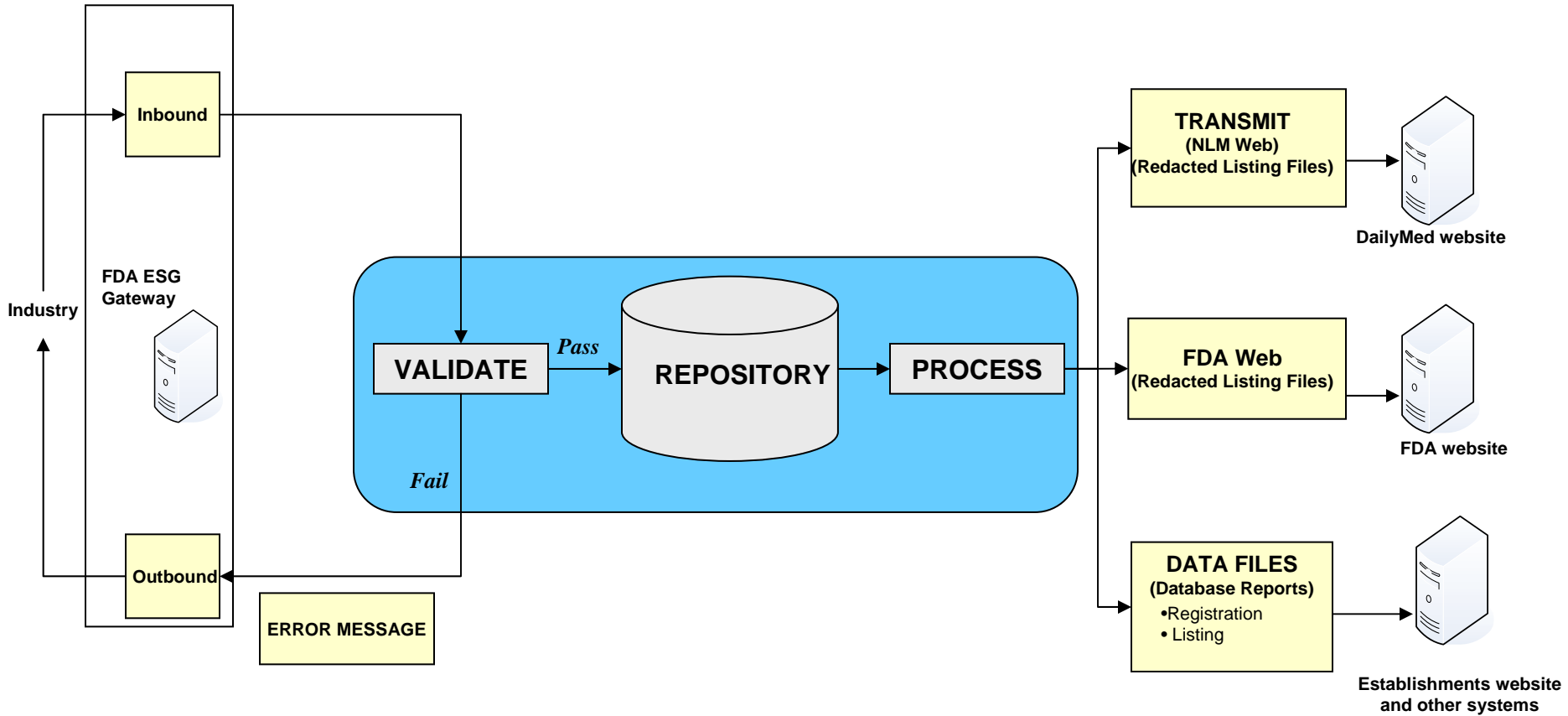
## Drug Listing ONLY



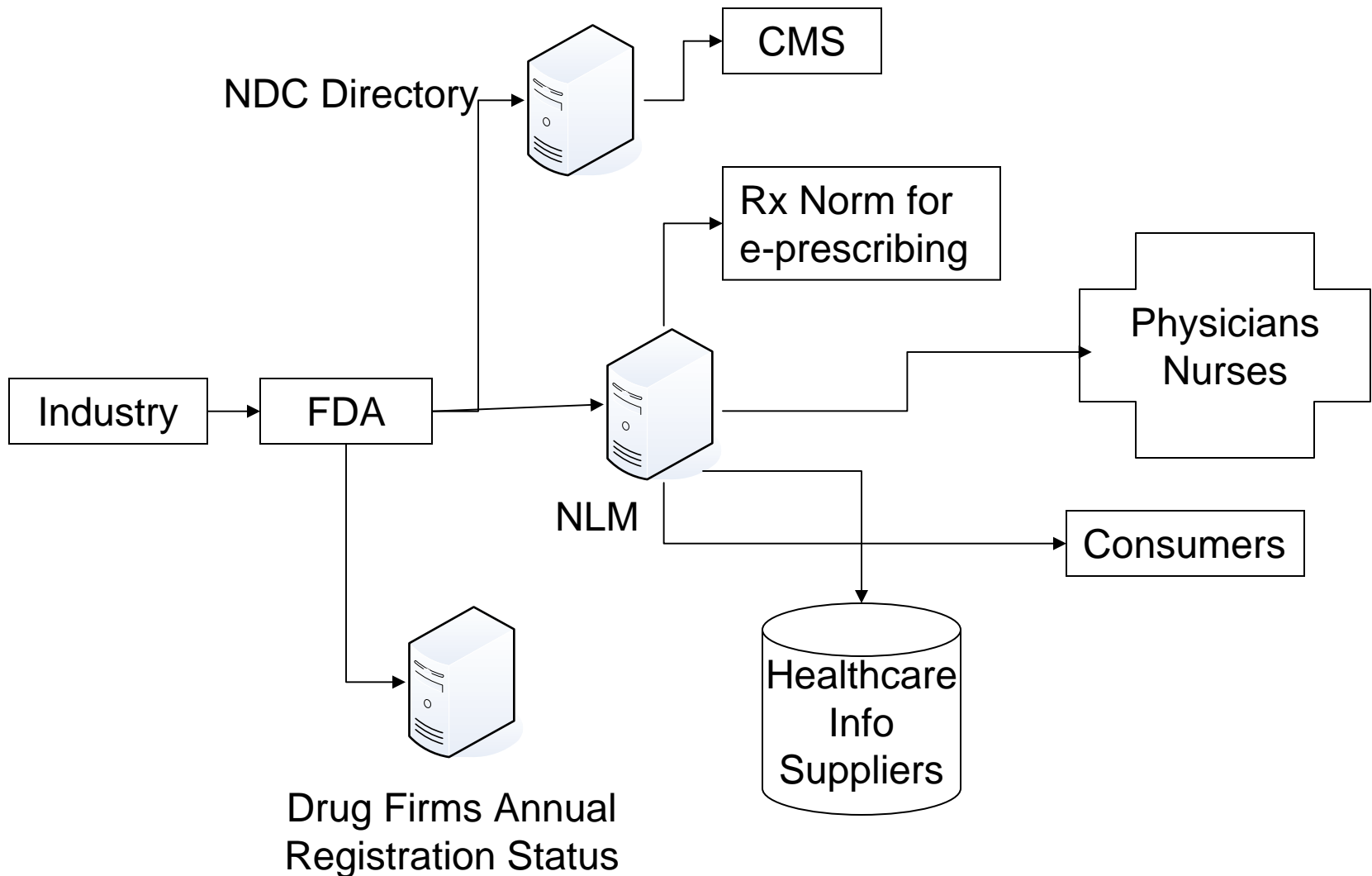
# Submitting the SPL as a Prior Approval and/or to Drug Listing



# eLIST



# Data Sharing





# Gateway Account

- Information regarding the FDA Electronic Secure Gateway to send SPL files (listing or registration)
  - Gateway checklist:  
<http://www.fda.gov/ForIndustry/ElectronicSubmissionsGateway/ucm114831.htm>
  - Digital certificates:  
[http://www.accessdata.fda.gov/esg/userguide/webhelp/Digital\\_Certificates.htm](http://www.accessdata.fda.gov/esg/userguide/webhelp/Digital_Certificates.htm)
  - Gateway Tutorials:  
<http://www.fda.gov/ForIndustry/ElectronicSubmissionsGateway/ucm165609.htm>

# PET Drug Core SPL Templates or SPL Xforms

- SPL Xforms available at no cost
  - Specific PET templates are included in the SPL Xforms
- SPL author (including SPL conversion vendors) can download templates of the PET drug SPL files
- Xforms and downloadable SPL templates are accessible via this hyperlink:

<http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/ucm241316.htm>

# Demo

# Submitting Files via FDA Gateway

WebTrader Help Logout

## Send document

Select who will receive the document

Gateway: FDATST

Center:  **Select the "OC" center**

## Select the contents of the submission

Enter a path to a file or a directory. If a directory is entered, then the entire contents of the directory will be included in the submission. All the paths stored in the submission will be relative from the provided directory path unless an alternate root directory is entered.

Path:  **Browse...** **Ensure that you are submitting SPL in a folder (file name should not appear in the path field)**

Root directory:  **Browse...**

Submission type:  **Select "SPL" as the submission type**

## Select a signing certificate

Current file: M:\SPL\_Main\gateway\Lonnie Smith\Lonnie Smith.p12

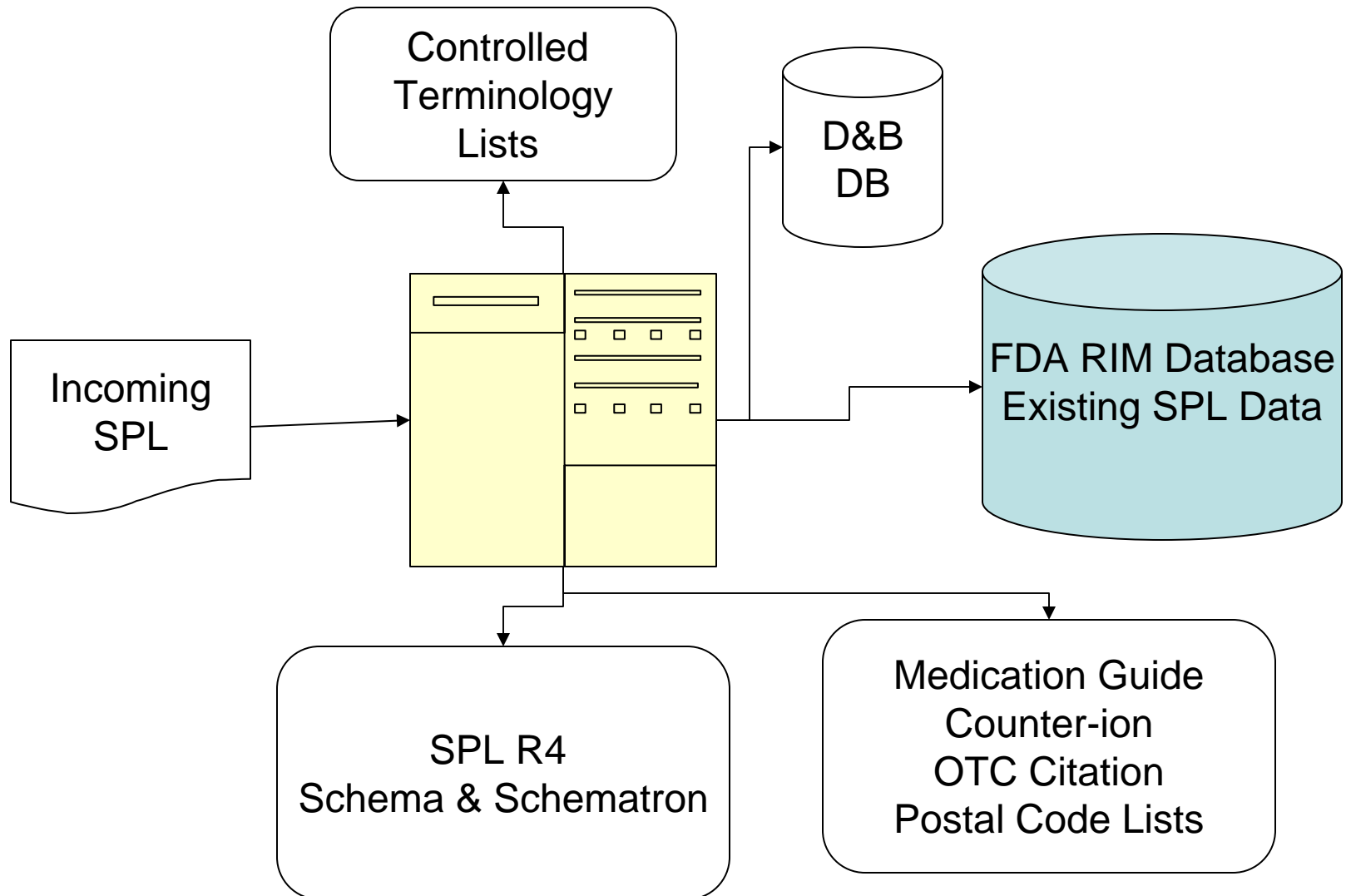
New file:  **Browse...**  
MyCertificate.p12 or MyPrivateKey.pfx

**Send**

# Updating SPL Document Tracking Information

- **Use**
  - **new** id root
  - **new** version number
  - original setId
  - appropriate effective time
- **Misplaced SetID/SPL File**
  - E-mail core ID to [spl@fda.hhs.gov](mailto:spl@fda.hhs.gov)
- Include contact person's name and DUNS Number which were included in original SPL file

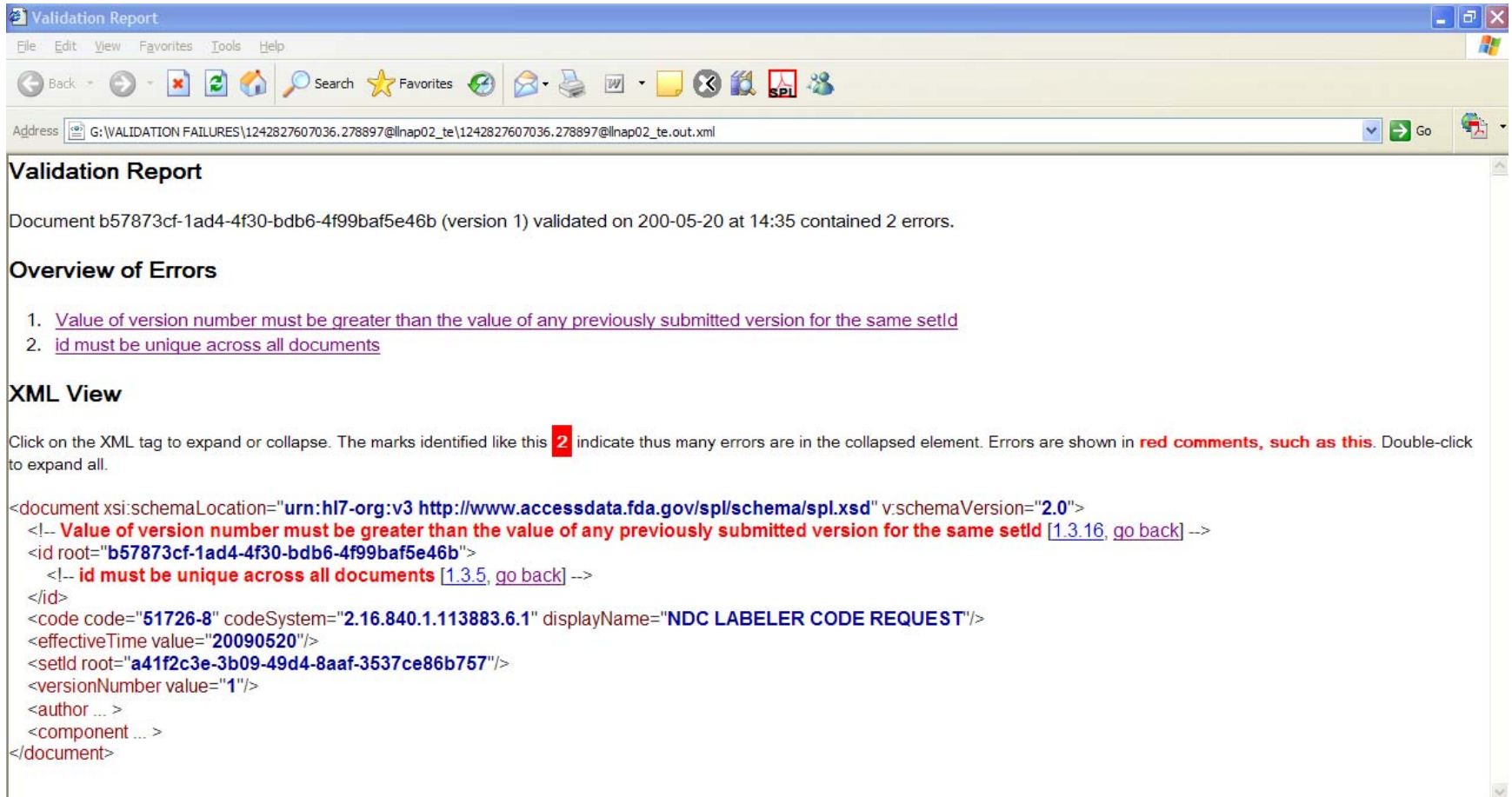
# Validation Model



# Validation Error Notifications

- Transmitted via FDA Gateway to submitter
- Transmissions occur within 36 hours (business days)
- In the form of a 2nd or 3rd acknowledgment
  - 2nd acknowledgment – system-generated message
  - 3rd acknowledgment – manually generated message with additional notes
- No 2nd or 3rd acknowledgment within 24 hours usually denotes that submission was accepted

# Sample System Generated Validation Report



**Validation Report**

Document b57873cf-1ad4-4f30-bdb6-4f99baf5e46b (version 1) validated on 200-05-20 at 14:35 contained 2 errors.

### Overview of Errors

- [Value of version number must be greater than the value of any previously submitted version for the same setId](#)
- [id must be unique across all documents](#)

### XML View

Click on the XML tag to expand or collapse. The marks identified like this **2** indicate thus many errors are in the collapsed element. Errors are shown in **red comments, such as this**. Double-click to expand all.

```
<document xsi:schemaLocation="urn:hl7-org:v3 http://www.accessdata.fda.gov/spl/schema/spl.xsd" v:schemaVersion="2.0">
  <!-- Value of version number must be greater than the value of any previously submitted version for the same setId [1.3.16, go back] -->
  <id root="b57873cf-1ad4-4f30-bdb6-4f99baf5e46b">
    <!-- id must be unique across all documents [1.3.5, go back] -->
    </id>
    <code code="51726-8" codeSystem="2.16.840.1.113883.6.1" displayName="NDC LABELER CODE REQUEST"/>
    <effectiveTime value="20090520"/>
    <setId root="a41f2c3e-3b09-49d4-8aaf-3537ce86b757"/>
    <versionNumber value="1"/>
    <author ... >
    <component ... >
  </document>
```

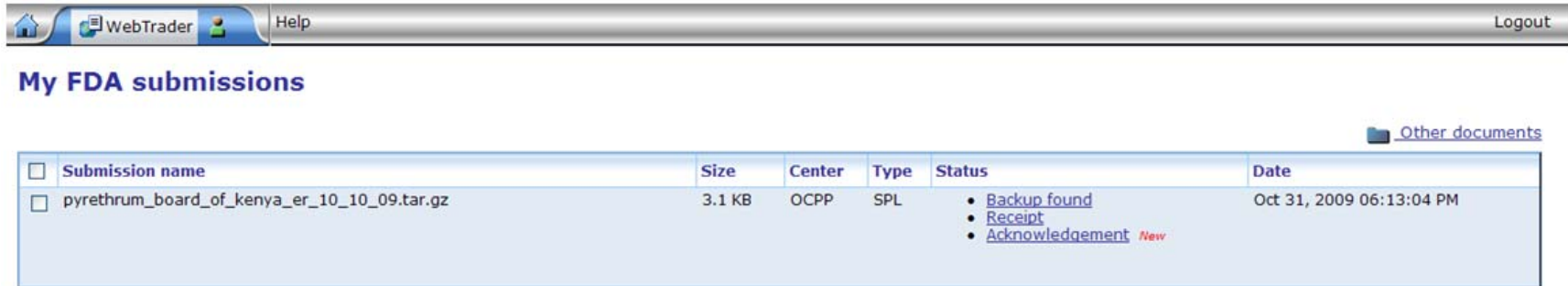


# Test Your SPL R4 Docs

- Provision of SPL R4 Validator Tool
- Test SPL R4 files prior to submission
- Discover ~90 – 95% of validation errors prior to submission.
- Schematron technology – permits quick updates to validation procedures
- FDA in collaboration with Pragmatic Data made available a validation tool:  
[Pragmatic Validator Lite™](#)

# **Locating the Gateway Core ID**

# Log onto FDA Gateway




The screenshot shows the FDA Gateway WebTrader interface. At the top is a navigation bar with a home icon, 'WebTrader' text, a user icon, 'Help', and a 'Logout' link. Below this is a section titled 'My FDA submissions'. To the right of this section is a link for 'Other documents'. The main content is a table with columns: Submission name, Size, Center, Type, Status, and Date. One submission is listed: 'pyrethrum\_board\_of\_kenya\_er\_10\_10\_09.tar.gz' with a size of 3.1 KB, center OCPP, and type SPL. The status column contains a bulleted list of links: 'Backup found', 'Receipt', and 'Acknowledgement' (marked as 'New'). The date is 'Oct 31, 2009 06:13:04 PM'.

<input type="checkbox"/>	Submission name	Size	Center	Type	Status	Date
<input type="checkbox"/>	pyrethrum_board_of_kenya_er_10_10_09.tar.gz	3.1 KB	OCPP	SPL	<ul style="list-style-type: none"><li>• <a href="#">Backup found</a></li><li>• <a href="#">Receipt</a></li><li>• <a href="#">Acknowledgement</a> <i>New</i></li></ul>	Oct 31, 2009 06:13:04 PM

- Log onto the FDA Gateway
- Select the “My FDA submissions” or “Other documents” hyperlinks

# Selecting the File w/Core ID

Center	Type	Status	Date
OCPP	SPL	<ul style="list-style-type: none"><li>• <a href="#">Backup found</a></li><li>• <a href="#">Receipt</a></li><li>• <a href="#">Acknowledgement</a> <i>New</i></li></ul>	Oct 31, 2009 06:13:04 PM



Click the "Acknowledgment" hyperlink

- The **first** "Acknowledgment" link should take you to window with core ID.

# Finding the Core ID

The screenshot shows a table with columns: Size, Center, Type, Status, and Date. The first row is highlighted, showing a 3.1 KB document from OCPP, Type SPL, with links for Backup found and Receipt, dated Oct 31, 2009 06:13:04 PM. Below the table, an 'Acknowledgment' window is open, displaying a 3 KB document. The window title is 'ci1257027185381.4044@lntap02\_te.txt'. The email details are: From: FDATE, To: Lonnie Smith (FDA), Date: Oct 31, 2009 06:16:03 PM EDT, Submission messageID: <7346727.1257027182095.JavaMail.smithlo@cdl0080685>. A 'View document' link is at the bottom. An arrow points to the Core ID in the window title, with the text 'This is the core ID' below it.

Size	Center	Type	Status	Date
3.1 KB	OCPP	SPL	<a href="#">Backup found</a> <a href="#">Receipt</a>	Oct 31, 2009 06:13:04 PM

close

ci1257027185381.4044@lntap02\_te.txt

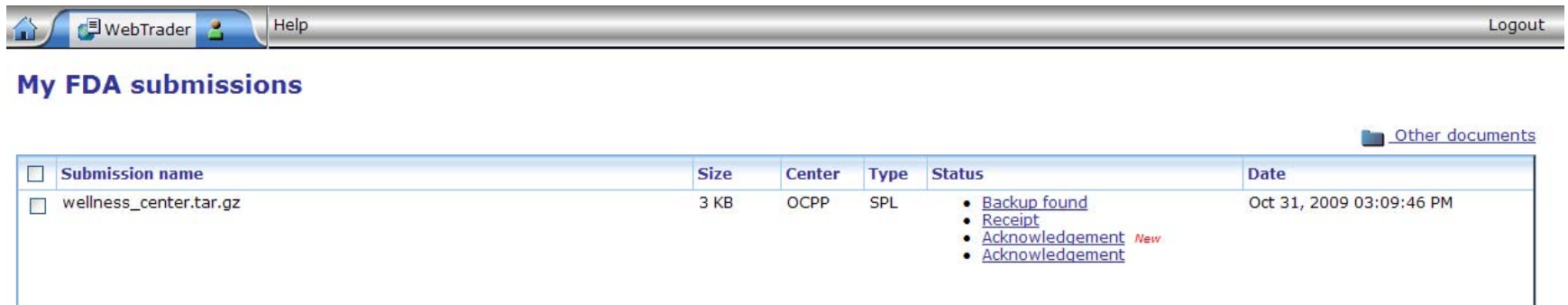
From: FDATE  
To: Lonnie Smith (FDA)  
Date: Oct 31, 2009 06:16:03 PM EDT  
Submission messageID: <7346727.1257027182095.JavaMail.smithlo@cdl0080685>  
[View document](#)

This is the core ID

- After selecting the “Acknowledgment” hyperlink, window should display.
- Core ID is located in top left of “Acknowledgment” window. (.txt is not part of the actual core ID)
- Use this core ID to reference submission when communicating with FDA about status or issue with SPL document.

# **Downloading Error Messages**

# Finding Error Messages



The screenshot shows the 'My FDA submissions' page in the FDA Gateway. At the top is a navigation bar with 'WebTrader', 'Help', and 'Logout' links. Below the bar, the title 'My FDA submissions' is displayed. To the right of the title is a link for 'Other documents'. The main content is a table with columns: Submission name, Size, Center, Type, Status, and Date. A single submission is listed: 'wellness\_center.tar.gz' (3 KB, OCPP, SPL). The Status column for this submission contains a bulleted list of links: 'Backup found', 'Receipt', 'Acknowledgement' (marked as 'New'), and another 'Acknowledgement' link.

<input type="checkbox"/>	Submission name	Size	Center	Type	Status	Date
<input type="checkbox"/>	wellness_center.tar.gz	3 KB	OCPP	SPL	<ul style="list-style-type: none"><li>• <a href="#">Backup found</a></li><li>• <a href="#">Receipt</a></li><li>• <a href="#">Acknowledgement</a> <i>New</i></li><li>• <a href="#">Acknowledgement</a></li></ul>	Oct 31, 2009 03:09:46 PM

- Logon to the FDA Gateway
- Select the “My FDA submissions” or “Other Documents” hyperlinks

# Selecting Error Message

Size	Center	Type	Status	Date
3 KB	OCPP	SPL	<ul style="list-style-type: none"><li>• <a href="#">Backup found</a></li><li>• <a href="#">Receipt</a></li><li>• <a href="#">Acknowledgement</a></li><li>• <a href="#">Acknowledgement</a> <span>New</span></li></ul>	Oct 31, 2009 03:09:46 PM



Click on second (or third) "Acknowledgment" hyperlink

- Receipt of a second or third “Acknowledgment” hyperlink is indicative that there is an error with your submission.
- Click on second (and third, if available) “Acknowledgment” hyperlink.



# Opening Error Messages

The screenshot shows a web interface with a table of messages and a detailed view of one message. The table has columns: Size, Center, Type, Status, and Date. The first row shows a 3 KB message from OCPP, Type SPL, Status Backup found, Receipt, Acknowledgement New, and Date Oct 31, 2009 03:09:46 PM. Below the table, a detailed view of the message is shown, including the filename ci1257016187076.9279@lntap01\_te.xml, From: FDATEST, To: Lonnie Smith (FDA), Date: Nov 1, 2009 12:34:11 PM EST, and Submission messageID: <18012736.1257016184535.JavaMail.smithlo@cdl0080685>. A 'View document' hyperlink is at the bottom left of the detailed view, and a 'close' link is at the top right. An arrow points to the 'View document' link with the text 'Click "View document" hyperlink'.

Size	Center	Type	Status	Date
3 KB	OCPP	SPL	<ul style="list-style-type: none"><li>• <a href="#">Backup found</a></li><li>• <a href="#">Receipt</a></li><li>• <a href="#">Acknowledgement</a> <i>New</i></li></ul>	Oct 31, 2009 03:09:46 PM

[close](#)

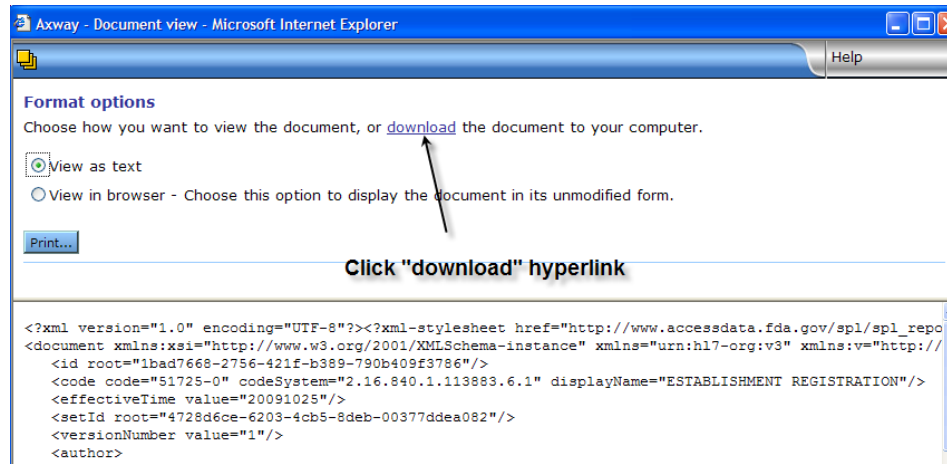
ci1257016187076.9279@lntap01\_te.xml

From: [FDATEST](#)  
To: [Lonnie Smith \(FDA\)](#)  
Date: Nov 1, 2009 12:34:11 PM EST  
Submission messageID: <18012736.1257016184535.JavaMail.smithlo@cdl0080685>  
[View document](#)

Click "View document" hyperlink

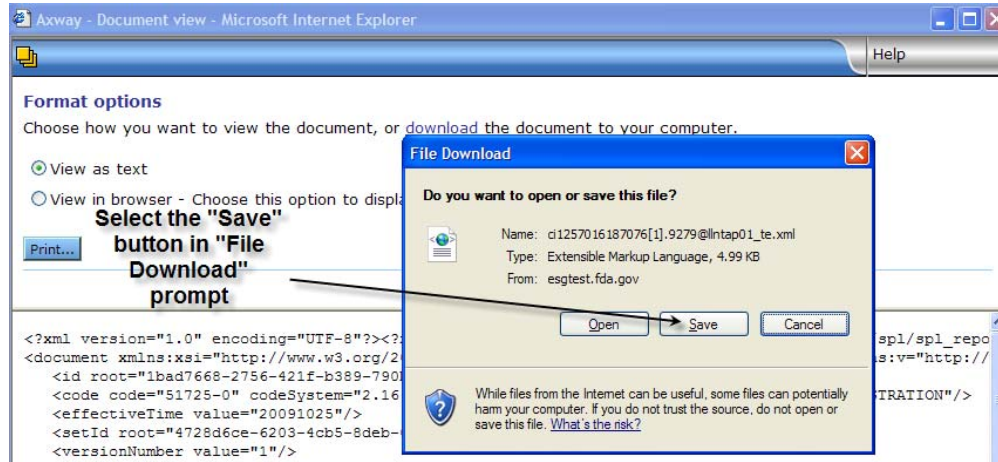
- Click the “View Document” located in the bottom left corner of Acknowledgment prompt window.

# Downloading Error Message



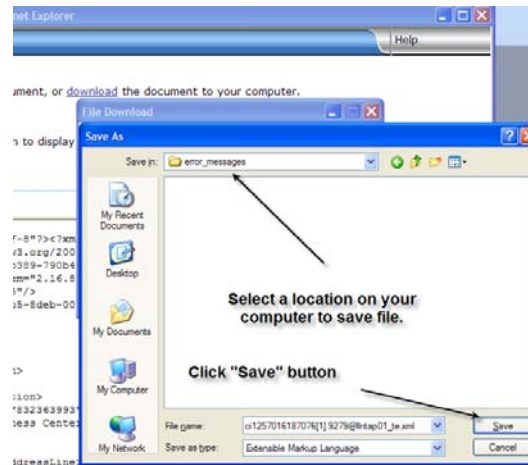
- Select the “download” hyperlink to download the error message to location on computer

# Saving the Error Message Document



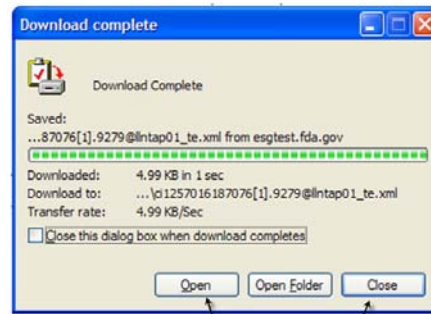
- Click the “Save” button in the “File Download” window prompt.

# Saving the Error Message Document cont...



- Navigate to preferred location on your computer in which to store the error message.
- Click the “Save” button to save message in preferred location.

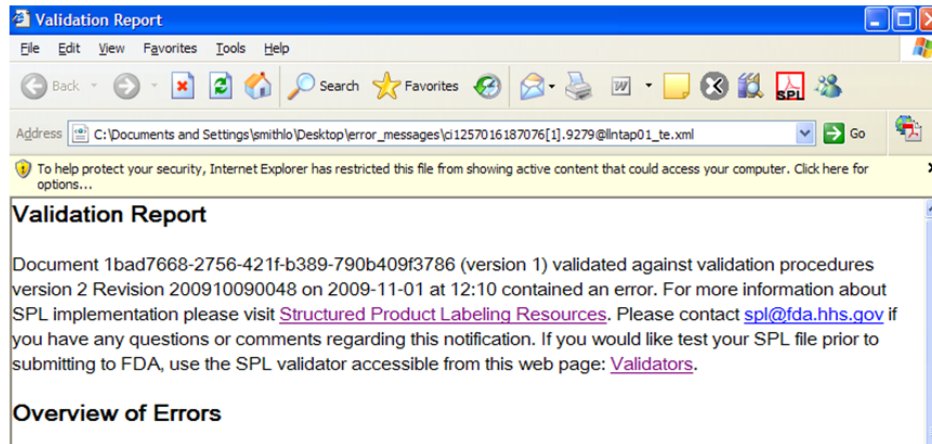
# Completing Download



Select "Open" or "Close" buttons

- You can open the message from the "Download complete" window prompt
- You can also close the window and directly open from location on your computer where message was stored.

# Review the Error Message



- Review the error message

# Stay Informed

- Join FDA Data Standards Council listserv
- <http://www.fda.gov/ForIndustry/DataStandards/default.htm>



The screenshot shows the FDA Data Standards Council website. At the top is the U.S. Department of Health & Human Services header with the www.hhs.gov URL. Below this is the FDA U.S. Food and Drug Administration logo and a search bar. A navigation bar lists various FDA categories: Home, Food, Drugs, Medical Devices, Vaccines, Blood & Biologics, Animal & Veterinary, Cosmetics, Radiation-Emitting Products, and Tobacco Products. The 'For Industry' section is highlighted, with a breadcrumb trail: Home > For Industry > Data Standards. On the left is a 'Data Standards' sidebar menu with links to Validators, Data Council, Structured Product Labeling, Individual Case Safety Reports, and Regulated Product Submission. The main content area is titled 'FDA Resources for Standards' and features a sign-up link for email updates, a paragraph describing the council's role, and a link to 'Structured Product Labeling'.

U.S. Department of Health & Human Services www.hhs.gov

**FDA** U.S. Food and Drug Administration

A-Z Index Search  go

Home | Food | Drugs | Medical Devices | Vaccines, Blood & Biologics | Animal & Veterinary | Cosmetics | Radiation-Emitting Products | Tobacco Products

**For Industry** Email this page Print this page Change Font Size

Home > For Industry > Data Standards

Data Standards
Validators
Data Council
Structured Product Labeling
Individual Case Safety Reports
Regulated Product Submission

### FDA Resources for Standards

 Sign up for email updates. ←

The FDA Data Standards Council coordinates the evaluation, development, maintenance, and adoption of health and regulatory data standards to ensure that common data standards are used throughout the agency.

[Structured Product Labeling](#)

# SPL-related Technical Assistance/Questions

- Questions regarding **ANY** part of the SPL creation or submission process, please contact us.
- SPL e-mail account ([spl@fda.hhs.gov](mailto:spl@fda.hhs.gov))



# QUESTIONS